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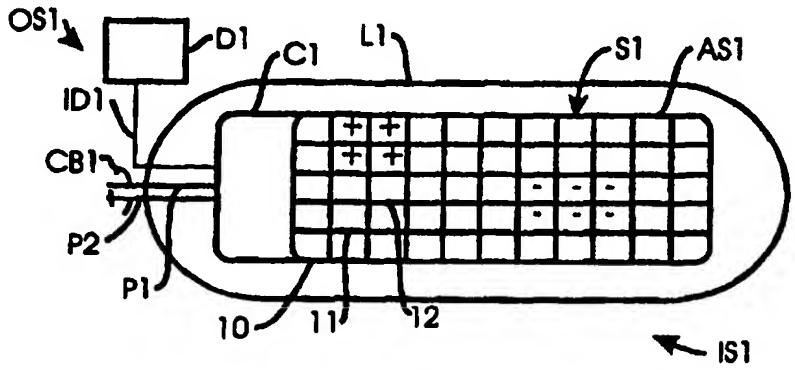

(57) Abstract

Implantable electrodes (10, 11, 12) adapted to interact with electrically excitable tissue are selected by an implantable, programmable controller (C1) that receives power from a main cable (CB1) and data from a data conductor (ID1) that identifies the stimulation and recording electrodes to be activated. The implantable controller enables electrical signals to be transmitted between a distal site of power generation and a selected subset of multiple electrodes with a minimum number of conductor wires.

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LIVING TISSUE STIMULATION AND RECORDING TECHNIQUES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to an implantable system for stimulating electrically excitable tissue within a patient and recording potentials of such tissue in the patient, and more particularly relates to such a system in which the stimulating and recording electrodes are selectable to reduce the number of conductors to a minimum.

Description of the Related Art

Often it is desirable with spinal cord or deep brain stimulation for pain relief or control of movement disorders to have many stimulation electrodes on a stimulation lead in order to place one or more cathodes and one or more anodes in optimal locations to produce benefits or minimize undesirable side effects. Implanted systems now use one to three leads and have between one and sixteen stimulation electrodes. Such systems typically must pass up to 20 milliamperes of current or more, involving current densities of 10 microcoulombs per square centimeter per phase or more. As a result, each electrode is connected to a sizable conductor in order to minimize energy losses due to impedance and to provide adequate strength to connect the wire to a power supply without substantial risk of breakage. Most current systems have the ability to program the polarity of each electrode. Due to size limitations and properties of conductors, it is difficult to have high reliability when there are eight, sixteen or more wires within a lead body that is implanted in a patient.

A lead with twenty to fifty or more stimulation electrodes could be useful for some therapies. Optimal combinations of cathodes and anodes could be selected for each patient. However, the use of this many electrodes has not been feasible in the past because of the size limitations imposed by the need to have a sizable conductor connected to each electrode. The present invention is directed to solving this problem.

A tripole lead is shown in PCT Publication No. WO95/19804 (27 July 1995). However, such a lead lacks the ability to reprogram electrodes, and clinical benefit is critically dependent on electrode positioning. This invention overcomes the

disadvantages of the foregoing lead by allowing changes in an effective stimulation area after implant by programming.

SUMMARY OF THE INVENTION

The invention is useful for interacting with electrically excitable tissue of a patient. According to the preferred embodiment, a group of implantable electrodes is adapted to interact with the tissue. A main cable extends from a first site to a second site adjacent the tissue. A source of data identifies one or more of the electrodes within the group, and a data conductor extends from the source of data to the second site. An implantable controller is responsive to the data for gating one or more of the electrodes to the main cable.

The invention enables electrical signals to be transmitted between the first site and one or more selectable electrodes within the patient with a minimum number of conductors. As a result, the number of electrodes implanted in the patient can be substantially increased in order to provide improved therapeutic effects. By minimizing the number of conductors, reliability is improved.

According to another embodiment of the invention, the electrodes include both recording electrodes and stimulating electrodes.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other advantages and features of the invention will become apparent upon reading the following detailed description and referring to the accompanying drawings in which like numbers refer to like parts throughout and in which:

Figure 1 is a top plan diagrammatic view of a preferred form of stimulation lead incorporating a stimulation assembly made in accordance with the present invention implanted within a patient and connected to a source of data;

Figure 2 is a side elevational view of the lead shown in Figure 1;

Figure 3 is a top plan diagrammatic view of a preferred form of recording assembly made in accordance with the present invention;

Figure 4 is a top plan diagrammatic view of modified form of lead in which the stimulation assembly of Figure 1 and the recording assembly of Figure 3 are combined using multiple controllers;

Figure 5 is a top plan diagrammatic view of another form of the invention employing multiple arrays of stimulation electrodes and an array of recording electrodes that are controlled by a single controller;

Figure 6 is a side elevational diagrammatic view of another form of the invention employing multiple electrodes on a nearly cylindrical lead;

Figure 7 is a diagrammatic end view of the lead shown in Figure 6 and rotated slightly from the view shown in Figure 6; and

Figure 8 is an enlarged view of Figure 7.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figure 1, a preferred form of flat paddle lead L1 suitable for implantation into a patient basically comprises a stimulation assembly S1 that includes a controller C1 and an array of stimulating electrodes AS1. Lead L1 is implanted at a site IS1 within a patient adjacent tissue to be stimulated. Array AS1 includes fifty-five electrodes, such as flat electrodes 10-12, arranged in a rectangular grid and electrically insulated from each other. The top surface of array AS1 is exposed to patient tissue at the surface of lead L1. Controller C1 is connected to a conductor ID1 over which data is provided, from a data source D1, as well as a cable CB1 comprising power conductors P1 and P2 for conducting stimulating current to electrode array AS1. P1 and P2 are connected to a power source not shown. Data source D1 is located at a site OS1 which could be located within the power source or at another location, usually subcutaneous. The data source may be a microprocessor including a memory for storing data that identifies electrodes to be activated and their polarities.

The Figure 1 embodiment is especially good for red skeletal muscle, since stimulation on such a muscle can only activate the muscle fibers directly under the cathode. Action potentials do not spread from muscle fiber to fiber, as they do in smooth muscle or cardiac muscle. Hence, a broad array of cathodes is useful to recruit many fibers of a red muscle.

Referring to Figure 2, lead L1 also may include another array of stimulating electrodes AS2, including flat electrodes such as 15-17, that is arranged on a side of

lead L1. The surface of the electrodes in assembly AS2 is exposed at the side of lead L1 to electrically stimulate tissue of a patient at site IS1.

Referring to Figure 1, under each stimulation electrode in arrays AS1 and AS2 is an electrical gate (not shown) which, when activated, allows that electrode to be connected electrically, and usually in parallel, to other electrodes of that polarity chosen by the data stored inside source D1. A signal is sent to controller C1 along conductor ID1 which identifies the electrodes to be activated. Some activated electrodes may become cathodes (-) and other electrodes may become anodes (+). The plus signs and minus signs in Figure 1 indicate electrodes which have been activated as anodes (+) and cathodes (-), respectively. The arrangement of anodes or cathodes on assembly S1 can be chosen by the patient or through investigation by clinicians to maximize the desired effects of stimulation, e.g., maximize pain relief, minimize spasticity, stop seizures, cause contraction of muscles, etc., and also to minimize undesirable side effects.

Still referring to Figure 1, power conductors P1 and P2 carry the stimulation current necessary in order to stimulate the electrically excitable tissue adjacent lead L1. For a monopolar stimulation, a single one of conductors P1 and P2 would suffice; but for bipolar stimulation, two power conductors (single channel), such as P1 and P2 are needed. For dual channel applications, three or four power conductors would be needed. One fewer wire may suffice if the power signal is modulated, and the modulation carries the data that otherwise would be carried by conductor ID1.

Still referring to Figure 1, each of electrodes in arrays AS1 and AS2 is between 1-6mm^2 in area, but other sizes also may be used. Typically, several neighboring electrodes are connected in parallel to have a combined surface area of 6-24mm^2, but other sizes also may be beneficial. The electrodes in arrays AS1 and AS2 are electrically conductive, and usually are made from a metal like platinum or iridium. In Figure 1, four electrodes have been programmed to be anodes (+) and six electrodes have been programmed to be cathodes (-).

The invention is useful in connection with electrically excitable tissue which includes both neural tissue and muscle tissue. Neural tissue includes peripheral

nerves, the spinal cord surface, the deep spinal cord, deep brain tissue and brain surface tissue. Muscle tissue includes skeletal (red) muscle, smooth (white) muscle, and cardiac muscle.

Figure 3 illustrates a preferred form of recording assembly R1 which includes a controller C2 and an array of recording electrodes RE1-RE5 electrically insulated from each other. Assembly R1 is implanted inside a patient at a site IS2. Controller C2 is provided with a conductor ID2 for transmitting data and a cable CB2 that includes power conductors P3 and P4, as well as an additional conductor RD1 used to transmit recorded and amplified tissue potentials received by one or more of conductors RE1-RE5. Conductor RD1 may be five separate conductors connected to electrodes RE1-RE5 or a single conductor on which potentials from electrodes RE1-RE5 are transmitted by time division multiplex techniques executed by controller C2. Alternatively, controller C2 might activate combinations of electrodes RE1-RE5 as stimulating electrodes to provide stimulation of tissue.

Recording assembly R1 can be used to record potentials in electrically excitable tissue. Controller C2 selects from among recording electrodes RE1-RE5, amplifies the signals received by the recording electrodes and sends the amplified signals over conductor RD1 to a recording instrument RC1. Controller C2 also could filter or otherwise process the signals. Instrument RC1 is located at another site, possibly OS1.

Referring to Figure 3, under each recording electrode RE1-RE5 is an electrical circuit consisting of an operational amplifier and a gating circuit to turn on or turn off the recording electrode. A recording electrode may be chosen with optimal signal strength and discrimination of the potential of interest. Two or more electrodes may be connected together in parallel to lower impedance or may be used differentially to better shape the recorded potential and remove noise signals.

Conductor ID2 is used to carry data from a data source, such as D1, to controller C2. In response to the data, controller C2 activates the desired electrodes and adjusts the amplification. Cable CB2 is used to bring power to controller C2. Conductor RD1 exits from the recording site IS2 to bring the amplified recorded

potentials to recorder RC1. The recording electrodes each typically have an impedance between 100,000 ohms and 1.5 megohms, but other impedances may be desirable. Figures 4 and 5 show the flexibility of controllers and arrays of stimulation electrodes and recording electrodes made in accordance with the invention. Referring to Figure 4, a lead L2 may comprise stimulating assembly S1 and recording assembly R1, as well as additional stimulating assemblies S2 and S3 that may be identical to assembly S1. Additional stimulating or recording assemblies may be added to S1 by the practitioner during implant. Conductor RD2 carries recorded potentials to a recorder, such as RC1 shown in Figure 3. Conductor RD2 may be an extension of conductor RD1, or may contain additional data resulting from processing done in controller C1 of assembly S1. For the configuration shown in Figure 4, controller C1 of assembly S1 may incorporate the functions of controllers C1 and C2 described in connection with Figures 1 and 3. Power is furnished to assemblies S2 and S3 by power conductors P1 and P2. A conductor ID3 communicates the data necessary to identify the stimulation electrodes within assembly S2 that need to be activated. A similar function is performed for assembly S3 by a data conductor ID4. Controller C1 processes the data on conductor ID1 in order to provide the appropriate data for assemblies S2 and S3 that is transmitted over conductors ID3 and ID4, respectively. With modulation of power signals on conductors P1 and P2, data conductors ID1, ID3 and ID4 may be unnecessary.

Referring to Figure 5, a lead L3 carries a controller C3 that is connected to array AS1 and an identical array AS2, as well as array AR1. Each of the recording electrodes in array AR1 is connected to controller C3 by one of conductors RL1-RL5. Each of the stimulating electrodes on assembly AS1 is connected to controller C3 by a cable CB3, which contains individual conductors connected separately to each of the electrodes in assembly AS1. Similarly, each of the stimulating electrodes in assembly AS2 is connected to controller C3 through a cable CB4. Controller C3 receives information on conductor ID1 which identifies the electrodes of assemblies AS1 and AS2 which are to be activated, as well as the polarity of the electrodes. Controller C3

activates the electrodes in assemblies AS1 and AS2 in the same manner described in connection with controller C1 of Figure 1.

The potentials transmitted by each of conductors RL1-RL5 are transmitted by controller C3 on a time division multiplex basis on output conductor RD2. RD2 may be connected to a recorder such as RC1 shown in Figure 3.

Figure 6 illustrates a generally cylindrical lead L4 carrying a controller C4 and an assembly of twenty-two stimulating electrodes AS3, including cylindrical electrodes 20 and 21 arranged as shown. Inside the body of lead L4 and mounted directly on electrodes 20 and 21 are corresponding electrical circuits CT1 and CT2. For stimulating assembly AS3, circuits CT1 and CT2 are electrical switches or gates which activate specified electrodes in the assembly in accordance with the data received on conductor ID1. If there is only one electrode at each longitudinal position of the lead, it could be a ring electrode. If there is more than one electrode at each longitudinal position, the electrodes at each longitudinal position could occupy equal sectors of the cross-section of lead L4. Then, by use of controller C4, only those electrodes nearest the excitable tissue could be used for stimulating or recording. A complex lead may be assembled in the operating room by plugging any number of cylindrical extensions onto lead L4 (Figure 6).

A recording assembly can be made in the same form as assembly AS3 shown in Figure 6. In this case, the electrodes would perform the same recording function described in connection with Figure 3. In such an embodiment, circuits CT1 and CT2 would be an amplifier and switchable gate that would transmit a tissue potential to controller C4.

Each of assemblies AS1-AS3 and AR1 may be silicon wafers, and thus rigid. Controllers C1-C4 may be conventional microcontrollers capable of executing instructions stored in memory. Other parts of leads L1-L4 may be flexible and inert, or flexible and carry wires, such as assemblies AS1, AS2 and AR1 of Figure 5. Flexible electrical circuits or ribbon cables also could be used to advantage.

Leads L1-L4 offer several advantages over known leads. One does not always know before implant what is the best strategy for lead placement and electrode

polarity. Leads L1-L4 allow the choice to be made later, and additional reprogramming at later dates, to give degrees of freedom in electrode position. It is sometimes useful to have five or more electrodes in a line (especially transverse to the spinal cord axis), so that two or three can be chosen at preferred medial/lateral positions. The preferred embodiments enable changes in effective stimulation area after implant by programming only.

One key need for practitioners is to position one or more electrodes on the "physiological midline". This means that pulses will give balanced effects, and not be biased unduly on one or the other side (near one or the other dorsal root). When using the location of the vertebral canal for lead placement, only 27% of the time is the paresthesia balanced (Barolat, G., Zeme, S. and Ketcik, B., Multifactorial analysis of epidural spinal cord stimulation, Stereotact. Funct. Neurosurg., 56 (1991) 77-103. The preferred embodiments allow the "physiological midline" to be found by testing, and to be programmed accordingly.

Recording of electrical signals is quite difficult, and very dependent on distance from the active tissue, direction of action potentials in axons, and especially on the area/impedance of the recording site (low impedance picks up potentials from larger distances, but signals are small). By picking the right locations of recording sites, and adding or subtracting neighboring site signals, the best signal can be obtained.

Being able to select and activate electrodes from a large number of possible sites provided by the preferred embodiments is valuable in case any site becomes unusable due to mechanical/electrical problems, scar tissue, etc. A near neighboring site might give almost as useful a result.

Currently the only way to select optimal electrode sites (beyond polarity choices) is by surgical positioning of the lead, which might be unreliable over time because positioning was done with the patient in one body position, and can change by migration of the lead. There have been proposals for leads that can have configuration changes, but these proposals do not offer the advantage of the preferred embodiments.

Advantageous uses for leads L1-L4 described in this specification include:

a. Over or in motor cortex or cerebellar cortex, where there are somatotopic maps of the body, and where fine control of the loci of excitation can help affect the movements or control of various body parts;

b. Over or in the sensory cortex, which also has a somatotopic map, so that paresthesia and/or motor effects can be adjusted to specific body parts;

c. In the thalamus, where there is a three-dimensional body map, and where there are lamina of cells that might best be activated (or partly activated) using many contacts and programming.

d. In deep tissue, where stimulation is advantageously achieved by cylindrical leads;

e. Transversely and over the cauda equina (nerves in the spinal canal descending from the tip of the cord) to enable great selectivity of stimulation;

f. In the cochlea, where there is insufficient space for many wires, but many channels are needed and where fine-tuning which sites along the cochlea get stimulated might lead to much better hearing;

g. Over branches of motor nerves or large nerves, to activate distinct fascicles; and

h. In the retina, where if a patient has no light going to the back of the eye, the preferred embodiment could stimulate in neural patterns as if light were going there in focus and being perceived.

The controller chips disclosed in this specification preferably are rigid, made on silicone, with a hermetically sealed cover. However, they may be quite small. All other parts of leads L1-L4 may be flexible.

Another advantage of leads L1-L4 is that a number of recording sites could be programmed in parallel to constitute a stimulation site which generally requires a low impedance and larger surface area. Several stimulation sites may be programmed together to reduce the impedance.

Those skilled in the art recognize that the preferred embodiments may be altered and modified without departing from the true spirit and scope of the invention

as defined in the appended claims. For example, the electrodes may be planar and of any shape (e.g., round, oval, and rectangular). The electrodes also may have three dimensional outer surface (e.g., cylindrical, spherical, semispherical or conical).

I claim:

1. Apparatus for interacting with electrically excitable tissue of a patient comprising in combination:

a group of implantable electrodes adapted to interact with said tissue;

a main cable adapted to extend from a first site to a second site adjacent said tissue;

a source of data;

a data conductor adapted to extend to said second site from a source of data identifying one or more of said electrodes within said group; and

implantable controller means responsive to said data for gating said one or more electrodes to said main cable, whereby electrical signals can be transmitted between said first site and said one or more selected electrodes with a minimum number of conductors.

2. Apparatus, as claimed in claim 1, wherein said group of electrodes comprises stimulating electrodes for stimulating said tissue.

3. Apparatus, as claimed in claim 1, wherein said group of electrodes comprises recording electrodes for conducting potentials found in said tissue.

4. Apparatus, as claimed in claim 3, wherein said recording electrodes are connected in parallel to form one or more stimulating electrodes.

5. Apparatus, as claimed in claim 1, wherein said source of data is adapted to be located at said first site and wherein said data conductor is adapted to extend from said first site to said second site.

6. Apparatus, as claimed in claim 1, wherein said controller means comprises a group of switchable gates interconnecting said main cable with said one or more selected electrodes.

7. Apparatus, as claimed in claim 1, wherein said group of implantable electrodes comprises a first plurality of stimulating electrodes for stimulating said tissue and a second plurality of recording electrodes for conducting potentials in said tissue, wherein said main cable comprises a power conductor and a recording conductor, wherein said source of data comprises a first source identifying one or more of said stimulating electrodes and one or more of said recording electrodes, and wherein said controller means comprises means for gating said selected one or more stimulating electrodes to said power conductor and for gating said selected one or more recording electrodes to said recording conductor.

8. Apparatus, as claimed in claim 7, wherein said controller means comprises multiplex means for transmitting signals between said one or more recording electrodes and said recording conductor by time division multiplexing.

9. Apparatus, as claimed in claim 7, wherein said first plurality of said stimulating electrodes comprises a first array of stimulating electrodes and a second array of stimulating electrodes spaced from said first array, said first array being connected to said controller means by a first cable and said second array being connected to said controller means by a second cable.

10. Apparatus, as claimed in claim 7, and further comprising a third plurality of stimulating electrodes spaced from said first plurality of stimulating electrodes and a second controller means displaced from said controller means for gating said third plurality of stimulating electrodes, said controller means and said second controller means being connected by a second main cable.

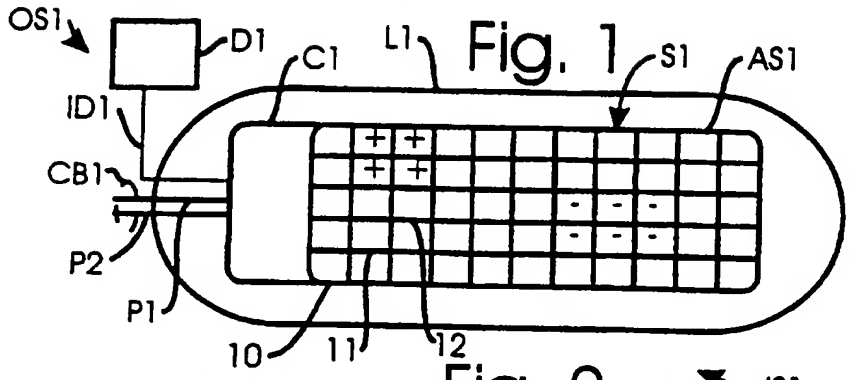


Fig. 1

Fig. 2

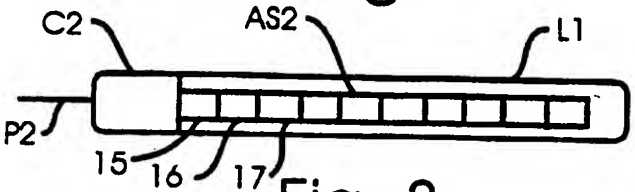


Fig. 3

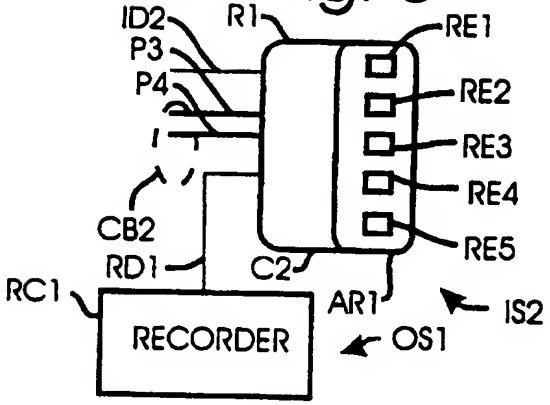


Fig. 6

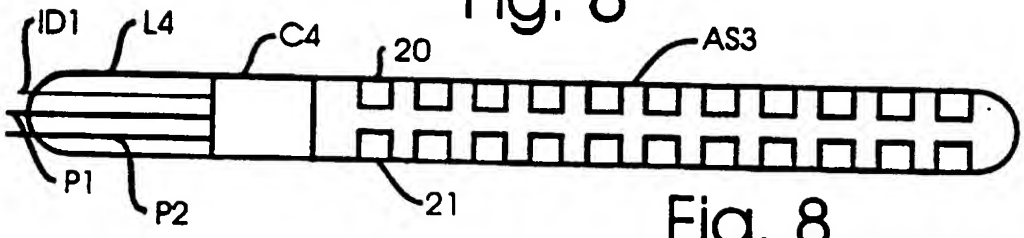
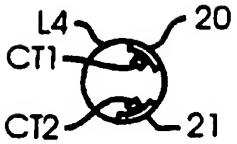


Fig. 8

Fig. 7



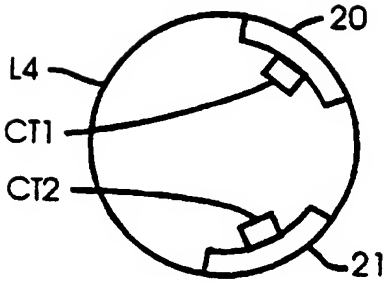


Fig. 4

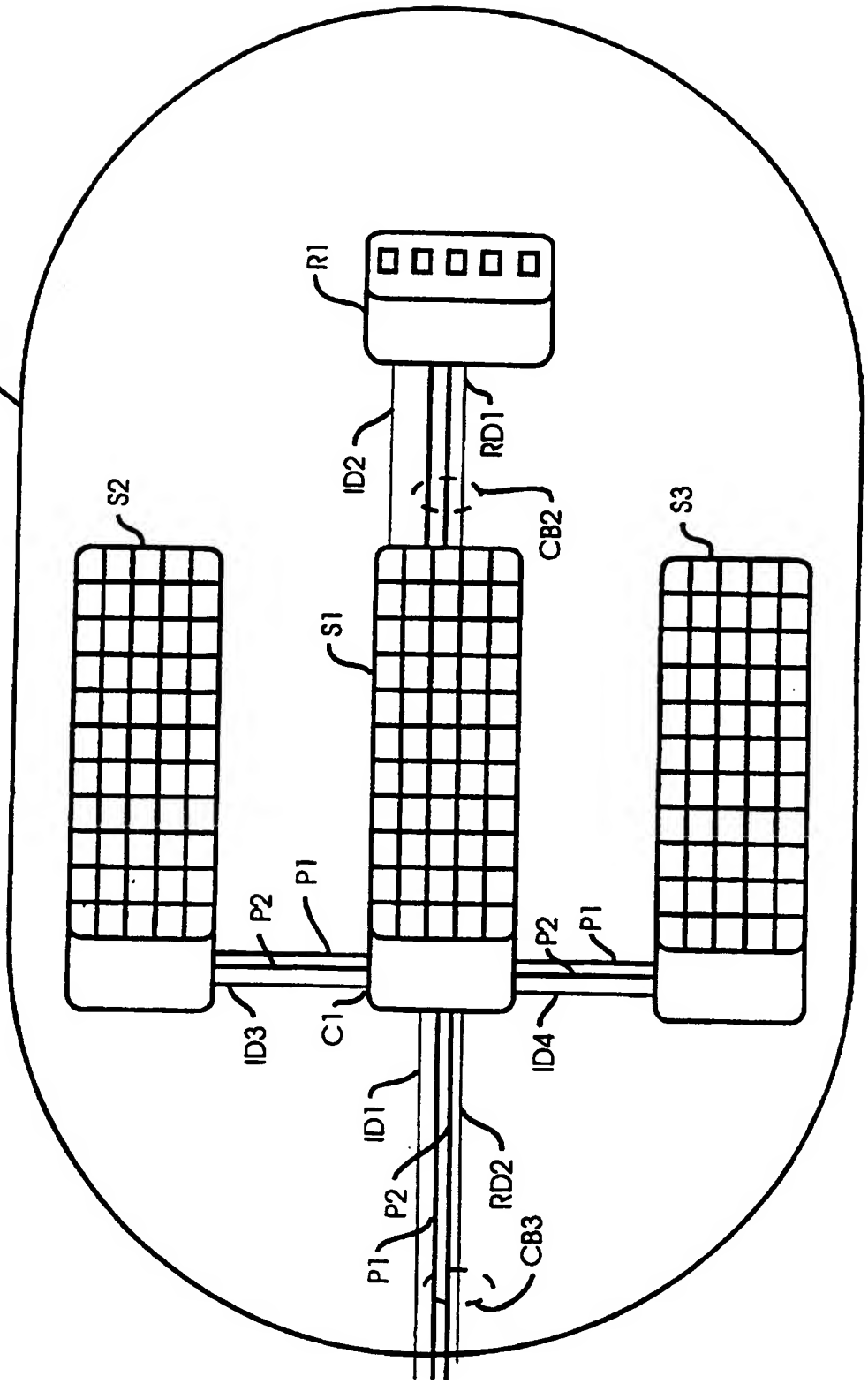
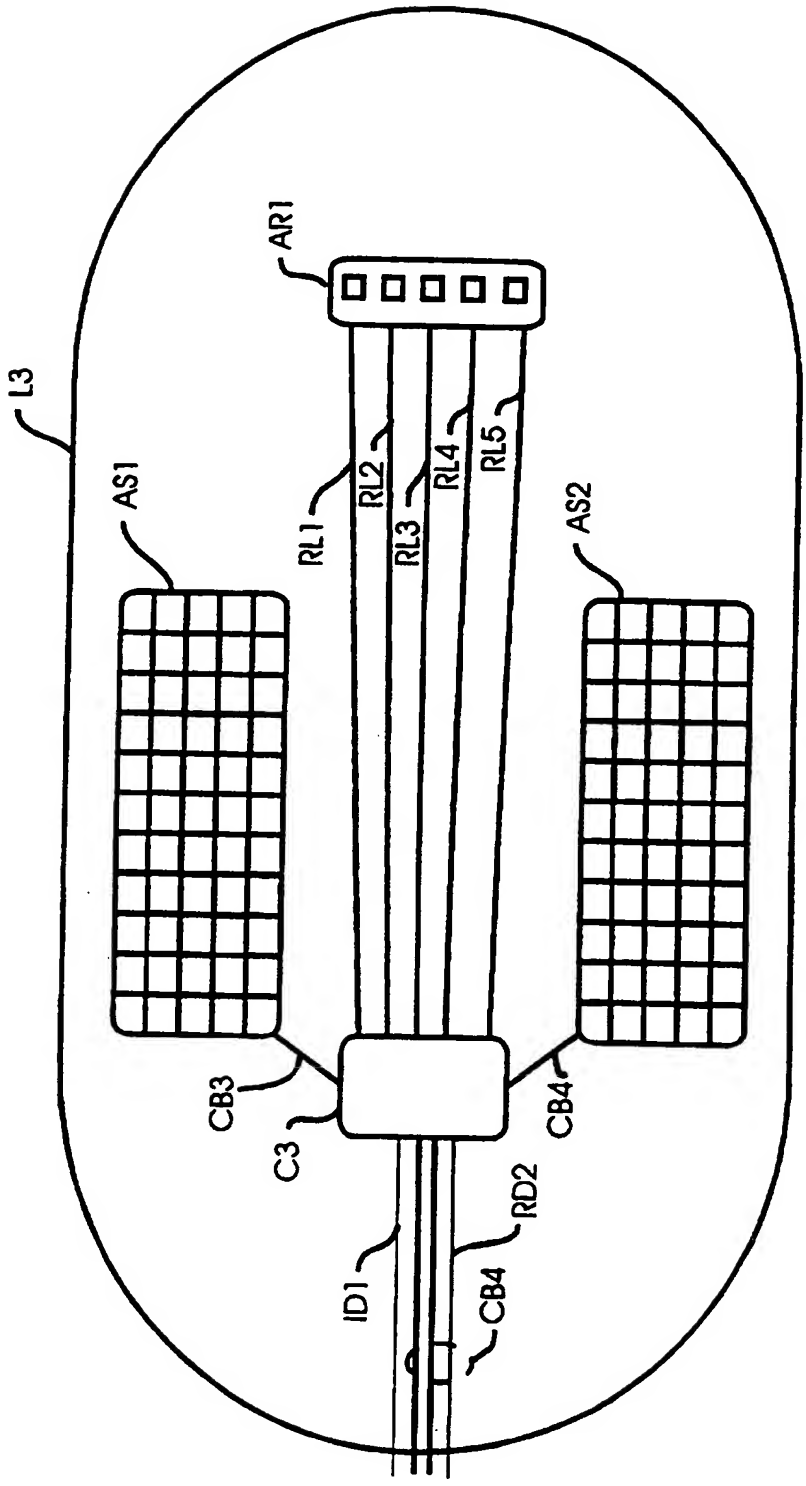


Fig. 5



INTERNATIONAL SEARCH REPORT

Internat Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/05 A61N1/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 325 870 A (KROLL MARK W ET AL) 5 July 1994 see column 2, line 14 - column 3, line 5; figures ---	1-4,7
A	EP 0 057 561 A (BIO MEDICAL RES LTD) 11 August 1982 see abstract; figures ---	1-3,5-8
A	WO 95 19804 A (MEDTRONIC INC ;HOLSHEIMER JAN (NL); STRUIJK JOHANNES J (NL)) 27 July 1995 cited in the application see page 3, line 11 - line 34; figures ---	1,2,7
A	WO 93 09844 A (MEDTRONIC INC) 27 May 1993 see abstract --- -/--	1-3,5-8

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 281 219 A (KALLOK MICHAEL J) 25 January 1994 see column 1, line 41 - line 60; figures -----	1-8

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INTERNATIONAL SEARCH REPORT

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